Welch Allyn Vision Screener Model VS100

Directions for Use

P/N 20146 Rev A

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The Welch Allyn Vision Screener

Welcome to the Welch Allyn Vision Screener. The Directions for Use are designed to assist you, the user, in making the most of your screening experience.

Intended Use

The vision screener is intended to measure the refractive power of the eye by measuring light reflexes from the retina. It also estimates pupil size, pupil distance and eye gaze deviation. It is intended for use on subjects six months of age through adults.

Indications for Use

The vision screener is indicated for use by healthcare professionals or under the direction of a healthcare professional to screen or evaluate individuals for potential refractive errors associated with poor vision.

Box Contents

The main shipping box contains the vision screener, Instructions for Use, and the Accessory box. The Accessory box contains:

1. AC Power Cord
2. Power Supply/Charger
3. Cleaning Cloth
4. Velcro Cable Straps

NOTE: Please do not discard the box and foam. Damages incurred by shipping the device in non-approved packing material will void the limited warranty (see page 33 for warranty details).

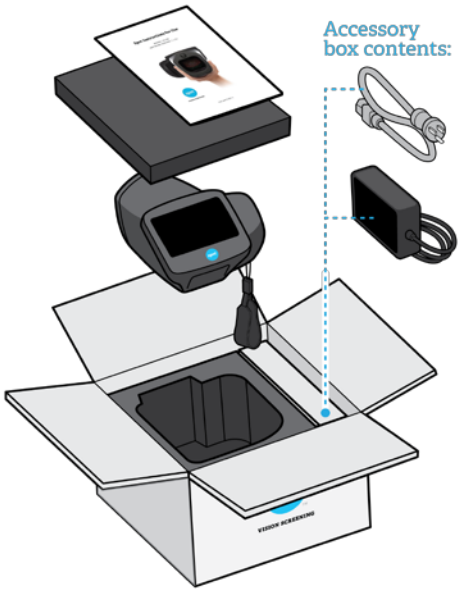

Figure 1

If you purchased a carrying case, place the foam from the shipping box inside the carrying case for safer transport. Do NOT store your vision screener in the foam or case while the Power cord is plugged in.

Device Description

The vision screener is a hand-held instrument with a video display on the rear of the unit that provides subject visualization and alignment. Video display also provides user interface functionality for data input and display. Operation is as simple as using a digital point and shoot camera. The vision screener provides visual and audible cues to attract subject's attention and gaze. The device provides a fast data collect for easy evaluation of the most difficult pediatric subjects of limited compliance. Each evaluation provides simultaneous binocular assessment of the subject's refraction, pupil size and gaze.

Basic Operation

Terminology – Device Details

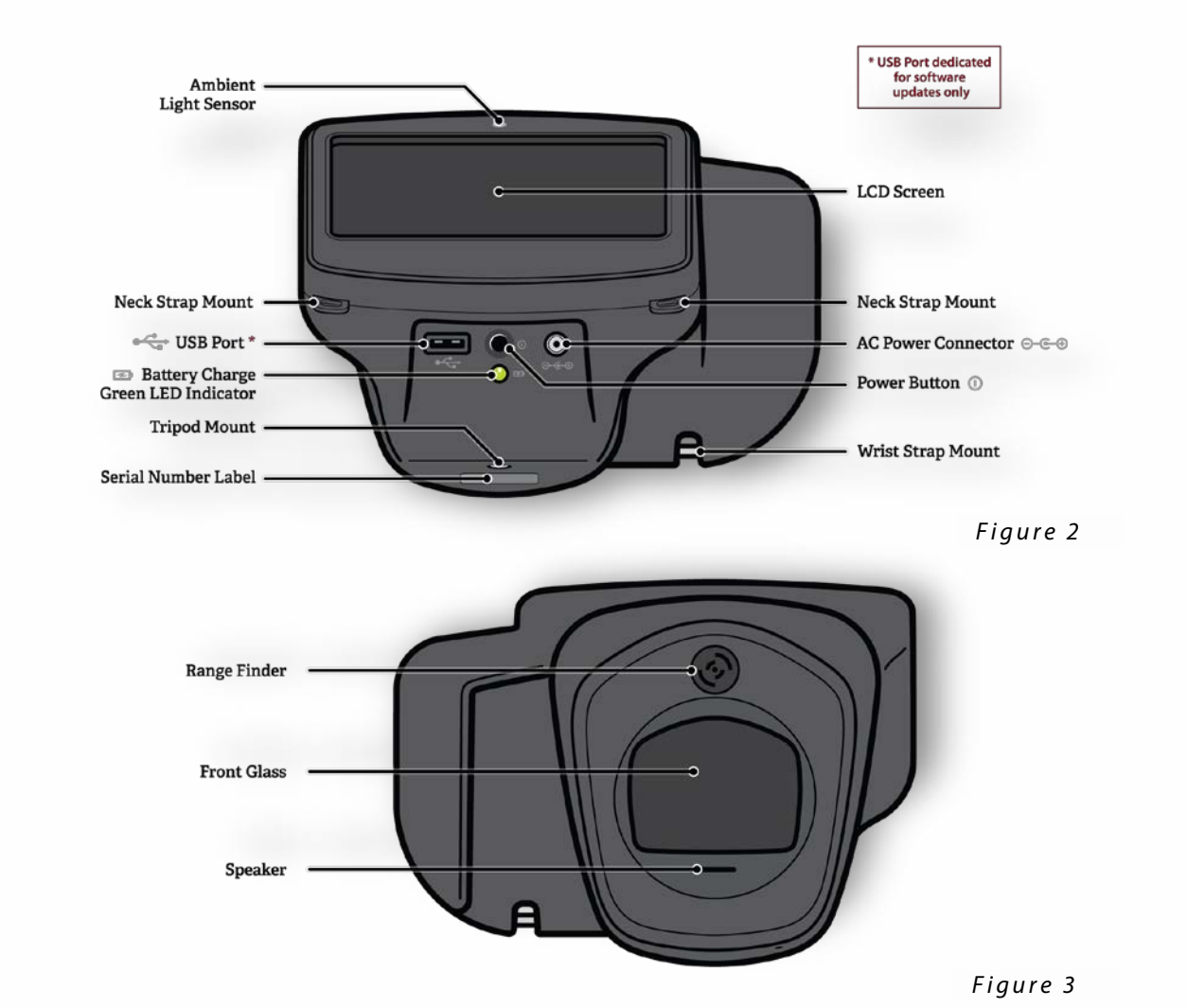

Figure 2

Figure 3

***NOTE**:* The USB port will only be used for software installations and import/export of vision screener data via a USB flash drive. No cable connection to any other device is permissible.

Basic Care

1. The vision screener is a precision instrument. DO NOT drop it or subject it to physical shock.
2. The vision screener is NOT waterproof. If you accidentally drop it into liquid or liquid is spilled on the device, contact Welch Allyn Support immediately. If minor water droplets are found on the device, wipe off with a soft dry cloth.
3. DO NOT leave the vision screener in excessive heat, such as in a car or in direct sunlight. High temperatures can cause the device to malfunction.
4. The vision screener contains precision electronic circuitry. Never attempt to disassemble the vision screener; this may result in bodily harm and will void any warranty.
5. DO NOT use cleaners that contain organic solvents to clean the vision screener's body or the front glass. Instead, use the provided cleaning cloth and for stubborn stains use with a small amount of water or a non-abrasive cleaner. Always keep the front glass free of fingerprints, dirt and dust.
6. When plugging the AC power connector into The vision screener, DO NOT force the power connector into the device as this may cause damage and will not be covered under warranty.
7. DO NOT store the vision screener in its case with the power cord plugged in, this could cause damage to both the power cord and the device. If plugged in, store in a location with no interference with the power cord.
8. DO NOT use the wrist strap as a means to carry the device; it is not designed to carry the weight of the vision screener.
9. DO NOT push or scratch the touchscreen display surface with anything stiff or rigid. A stylist is acceptable for use with the device.
10. DO NOT spill liquids on the vision screener. Please wipe off drops of liquid like saliva and water on LCD panel surface immediately.

Warnings

1. Changes or modifications not expressly approved by Welch Allyn could void the user's authority to operate the equipment.
2. The supplied AC cord set should be used exclusively. Replacement or substitution may only be done with a CSA or UL approved hospital-grade AC cord set.
3. The supplied power supply/charger may not be substituted and shall only be replaced by an approved unit supplied by Welch Allyn.
4. Interconnection of this medical device with other medical devices, medical systems or non-medical devices shall be evaluated to the requirements of CSA/IEC 60601-1 in the end use application.
5. This equipment is ESD sensitive; do not touch connector pins during use.
6. If the power cord or external power supply becomes damaged or its integrity is suspect, or the building power receptacle outlet is ungrounded, then the vision screener shall only be used with the internal battery power until replacement parts become available.
7. The operator shall not touch accessible conductive parts (ac/dc adaptor output connector, power input connector and USB port) and the subject simultaneously.

Screening Environment

For optimal screening results, screen in an environment with lower level subdued lighting. Be sure to eliminate or block any sources of sunlight and/or incandescent light from reflecting on the subject's eyes (See *Figure 4*). Florescent light is acceptable but note that the subject's pupil size can be affected and can decrease your chances of a successful screening.

> ***NOTE:*** A minimum pupil size of 4mm is required for screening to occur and may be difficult to achieve in a room with any light source. If the pupils are too small, the vision screener will notify you on screen to adjust the lighting in the room. For best results, subject's pupils should be 5mm or greater.

Figure 4

Getting Started

Charging

1. Connect provided AC cord set and power supply/charger together.
2. Gently lift the back of the vision screener to view the available connections.
3. Locate the DC power connector ⊖⊂⊕ on the vision screener and connect the power supply/charger (*see Figure 5*). The DC power connector on the power supply/charger will easily insert into the DC power connector on the vision screener. Using force to connect the power charger can damage the device and will void the warranty.
4. Plug the AC power cord into an available AC wall outlet to charge the device.

Powering the vision screener On and Off

1. To turn the vision screener on, press and release the power button (start-up process takes approximately 30 seconds). Once powered on, you will see the Main Menu
2. To turn the device off, press and hold power button for two seconds. A confirmation screen will appear to confirm shut down.

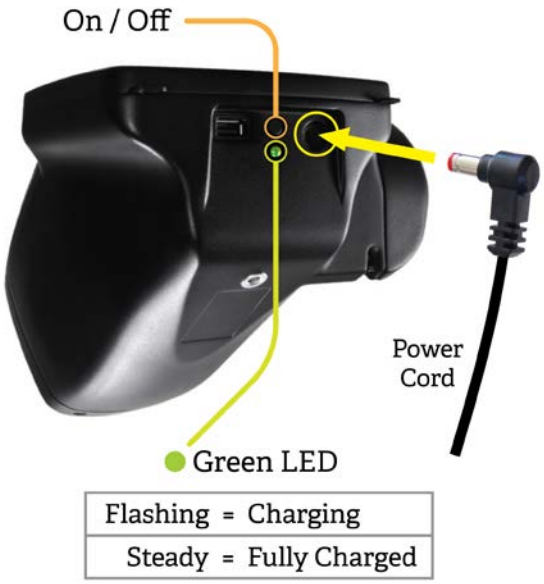

Figure 5

Tripod Mount

The vision screener can be mounted to a standard photographic tripod. A ¼-20 threaded mount located on the bottom of the device is available for attaching a tripod.

Helpful Hints

- **No activity on the vision screener**—After 60 seconds the screen will dim; after 5 minutes the screen will automatically turn black to conserve battery power. Tap the screen to 'wake up' the vision screener or press the power button. If the screen does not light up, plug in the power cord and try again.
- **Exporting/Delete Historical Records**—Verify you have successfully exported desired data to a USB drive before you select "Delete All Records".
- **Routinely Delete ALL Records from the vision screener**—Go to the History screen and select Clear All icon. Select "Delete All Records". You may also delete all Queued records.
- **Avoid Powering Off during a Screening**—Once the screening takes place, exit by selecting the button, then power down the device normally.
- **Input Screen**—Holding down the button on any input (keyboard) screen will delete all data from the field.
- **Low Battery**—When the battery level reaches a very low level, a notice will appear to the User indicating they should insert the power cable or the device will shut down. If no power cable is inserted, the device will automatically shut down due to low voltage of the battery.

User Operation

Main Menu – Home Screen

When the vision screener is powered on, the main menu or "Home Screen" will appear (*Figure 6*). If the vision screener is connected to a network, the network name and IP address will be visible in the upper left corner in the black bar.

Figure 6

Start: To begin the data entry and screening process, select the Start button, this will allow you to:

- Enter subject information such as ID, First and Last Name, Gender and DOB/Age (Required)
- Find queued subjects (exact match on the ID screen)
- Begin the screening process (Binocular and Monocular available)
- Review and print screening results

OR

Select an Age Range: To begin instant screening, with no personal subject data, select an age range of the subject from the Home screen. You will be able to enter subject data after the screening if desired.

Icons on bottom of screen:

- Queue – View, select or search for queued subjects from a list to begin the screening process.
- History – View already screened subjects (completed records).
- Tools – A variety of options to customize the vision screener.

Subject Information Screen

On the subject information screen *(Figure 7)*, confirm all data is correct. You can modify information by touching the field you wish to change. After the change is completed select "ok" and you will come back to the subject information screen. DOB/Age is required and will highlight in red if there

is no age or if it is not a valid birthdate or age (under 6 months). Select GO to begin the screening process.

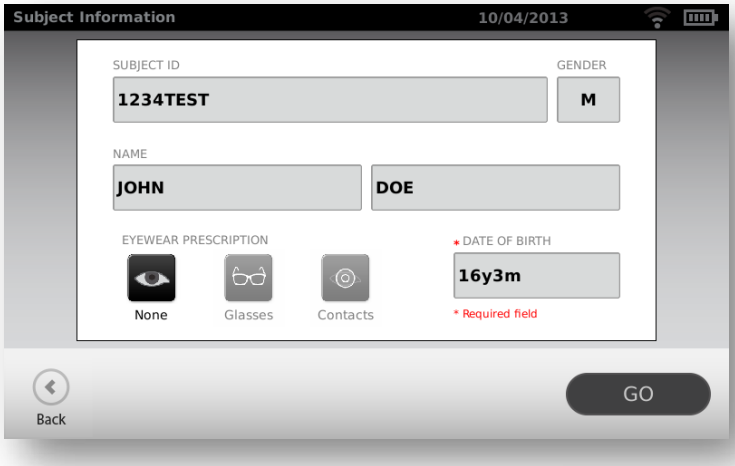

Figure 7

Screening a Subject

1. Position yourself approximately 1 meter from the subject, as shown in *Figure 8*.
    - If using a tripod, place the tripod approximately 1 meter from subject.
2. Start screening and slowly rotate the device upward to meet both of the subject's eyes. Adjust your distance from the subject until both eyes are clear on the screen.
    - With a tripod, adjust the tripods position up or down and side to side until the subjects eyes are in focus on the screen.

    ***NOTE**:* Keeping the vision screener even (on axis) with the subject's eyes will promote quicker results and help ensure you are not capturing other objects.
3. A blue screen indicates you are too close *or* too far from the subject.
4. Position yourself with one foot in front of the other, slowly rock forward and back until the screen turns grey, indicating you are in the capture range.
    - When using a tripod, move the tripod as needed to ensure focus on the subject's pupils until the screen turns grey.
5. Keep the vision screener device steady until the screening wheel appears, indicating the capture process is underway.
6. If you were unable to capture the subject's pupils with a successful screening, the measurement will be stopped, at this point you can retry, flag the record, try monocular mode or return to the "Home" screen.
7. If the pupils are too small, the device will notify you on screen to adjust the lighting in the room to promote larger pupil size.

How to Focus the vision screener

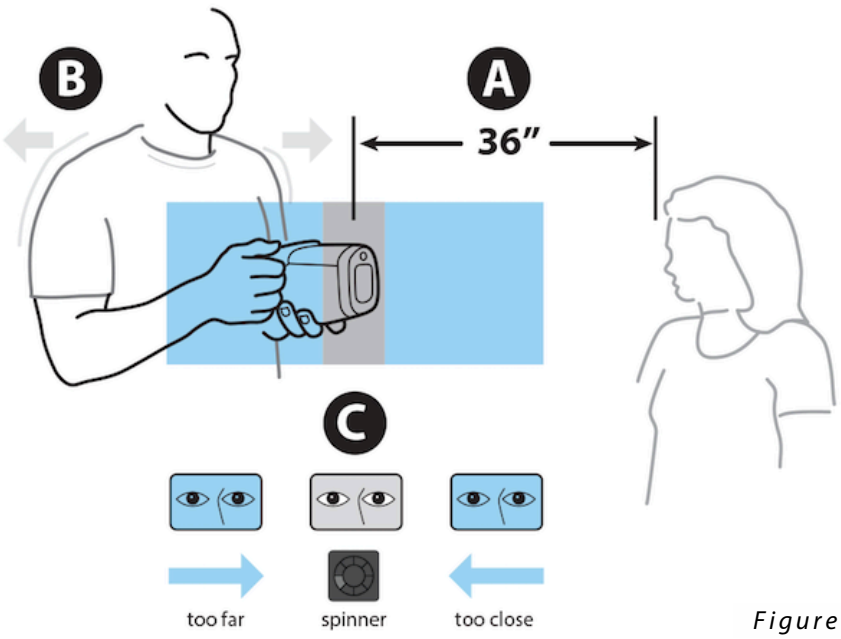

Figure 8

A. Position *Spot approximately* 36" away from subject.

B. Hold *Spot* close to body, and lean forward & backward until screen becomes GRAY.

C. Make small movements until the spinner appears on the GRAY screen.

Note: Eyes should be wide open and kept in center of frame for best results.

Monocular Mode

In monocular mode, you will be given the option to choose which eye to screen. This should be attempted when binocular screening does not capture the subjects' pupils.

1. Touch the side of the screen that corresponds with the eye you would like to screen. (OD = subjects right eye; OS = subjects left eye).
2. When complete, you can repeat the process with the other eye by choosing Monocular from the Results Menu.

Viewing the Results

- The results screen will appear at the end of the screening process *(Figure 9)*.
- Results that are out-of-range are indicated in red.
- All results viewing options are in the Tools menu under Results including; defaulting to a summary screen or the detailed results screen, hiding recommendations or measurements, cylinder convention options and raw or rounded data.

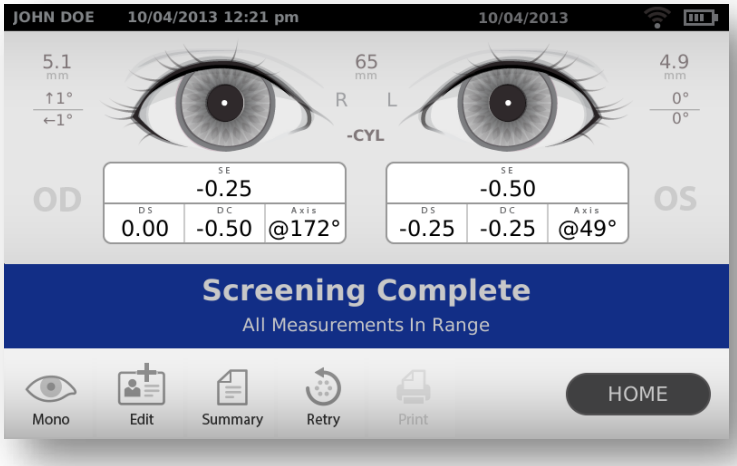

Figure 9

Understanding the Results

Figure 10 below outlines the results screen and what it shows you:

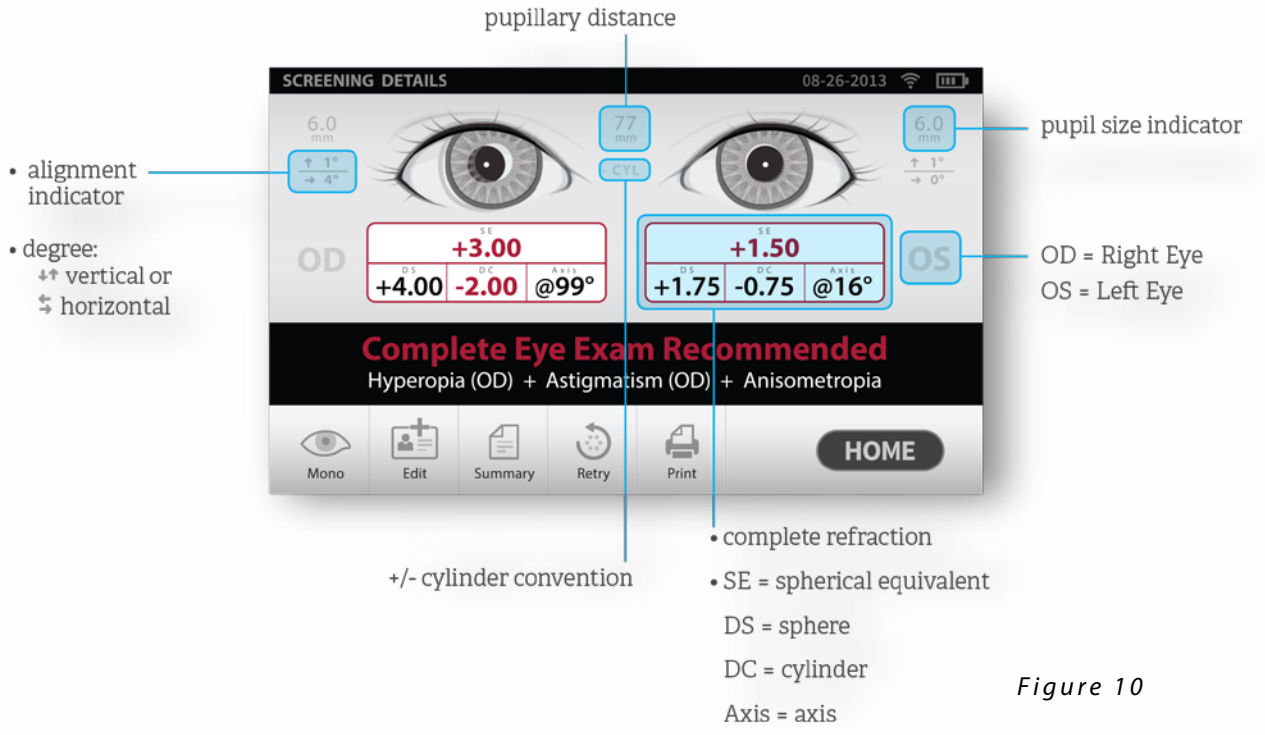

Figure 10

Tools

The “Tools” menu will allow you to customize and configure The vision screener with the following options:

Displays firmware version, software application version and serial number. Also displayed is a quick reference of important the vision screener features, including memory storage levels of the device

View the age-based criteria settings used for exam recommendations that are currently active on the vision screener.

Allows you to set the current date and time for your vision screener.

Enables you to import and export using an inserted USB storage device.

Location allows you to set a location for a screening and all subjects will be tied to that location.

Allows you to connect the vision screener to a wireless network. You can manually enter your network name (SSID), select the security type, and enter the passphrase for your network. From this page you can view and change your TCP/IP settings.

Allows you to configure a network printer and print a test page. It also lets you view printer status.

Allows you to configure how data is displayed on the Results screen when a screening is complete. This includes data format, cylinder convention, displaying or hiding measurements and recommendations, setting default screening display and screening time-outs.

Helps you set a security PIN for your device for added security. If enabled a PIN will be required whenever you start the device or upon waking it.

Activate the license on the device.

Gives you to the option calibrate the touchscreen on your device.

Wireless Network Configuration

1. From the "**Tools**" menu, select the **Network** icon.
2. Current network settings are displayed on the screen (*Figure 11*).
3. To add or edit any of the fields, see instructions below.
4. If they are correct, select ⊗ to be returned to the "**Tools**" menu.

Figure 11

To add/change the **network** name (SSID):

1. Touch the SSID Name field; a keyboard will appear.
2. Enter the SSID (case sensitive); select **"ok"** to save your changes and return the previous screen. "Ok" button will turn dark when changes have been made and are available to be saved.

To add/select the **security type**:

1. Touch the security type field.
2. Select the appropriate security type None, WEP, or WPA.

   NOTE*:* WPA option supports WPA Personal/WPA2 Personal.

To add/change the **passphrase (password)**:

1. Touch the passphrase button; a keyboard will appear (this is only available when the security field is set to WEP or WPA).
2. Enter the passphrase (case sensitive) and select "**ok**"

3. On the Network screen, select "**Ok**" to save changes, otherwise changes will not be applied.

To enable or disable the **wireless capabilities** on the vision screener:

1. Select the

"On/Off" button from the network menu.
2. You will be prompted to Disable or Cancel. If you Disable wireless, the device will need to be rebooted to turn Wireless On. After rebooting, go to Networks and select "On/Off" then confirm Enable. NOTE: Wireless must be on for printing to be enabled.

To view advanced **network settings**, select TCP/IP. From here, you can also view your current TCP/IP address as assigned by your network. For additional **network configurations**, select "Static" to manually configure your network address and settings. (Also available is the MAC address of your vision screener - *Figure 12*).

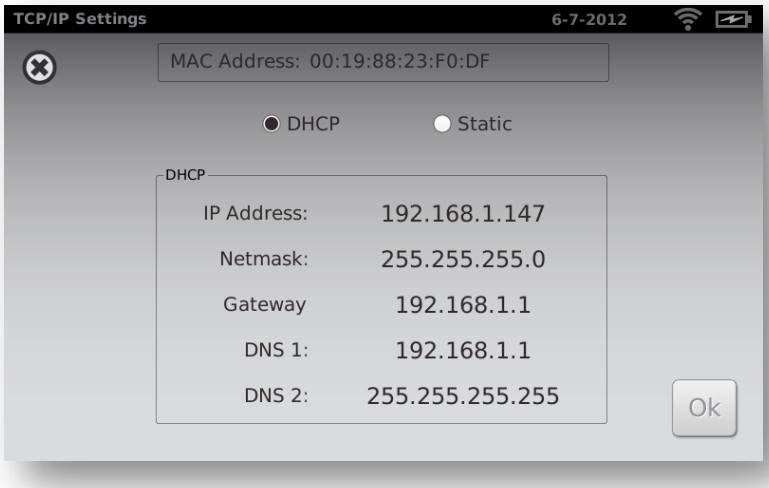

Figure 12

Printer Configuration

The vision screener is capable of connecting and printing to most network capable Hewlett-Packard (HP) printers. The vision screener also contains some generic PCL drivers that can be used with non-HP printers, as well as a custom driver that supports the Brother QL-720NW label printer.

NOTE: In order to install the QL-720NW on the vision screener, it must have QL-720 in its name on the network and you must select the driver labeled QL-720NW from the driver list. Use Brother DK2205 Continuous Length Paper Tape or equivalent.

1. From the "**Tools**" menu, select the printer icon.
2. The next screen will list the available printers on the vision screener. This is a list of all printers already added to the vision screener. (*Figure 13*).

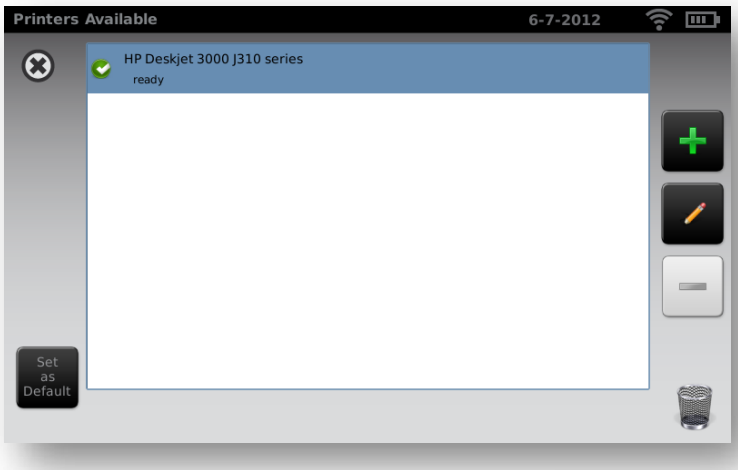

Figure 13

To **select or change a default printer**:

1. From the printer list, find and select the desired printer (it will auto-highlight in blue.) If more than one printer is listed, touch *Set as Default* button for the highlighted printer.

To **add a printer** to your list, press the Add button (Refer to "Adding a Printer" section below).

To **configure a printer**, select a printer then press the Edit button to view printer Status or print a test page.

To **delete a printer**:

1. Select the printer from the available printer list; touch the button to delete.
2. A pop-up will appear asking you to confirm deletion of the printer.

To **reset the printer system** which will delete all printers:

1. Touch the trashcan icon.
2. A pop-up will appear; select "Delete". This will remove all current printer configurations.

Adding a Printer

1. From the "Printers Available" screen, select the plus sign to add a printer. *(Figure 13)*.
2. If any printers are found on the network, they will appear in the list. If your printer is not shown, select "+ Add New Printer" at the top of the screen (*Figure 14*) or you can select the printer you wish to add then the **continue icon**

   NOTE: Make sure you are connected to a wireless network with available printers for the vision screener to show printers available.

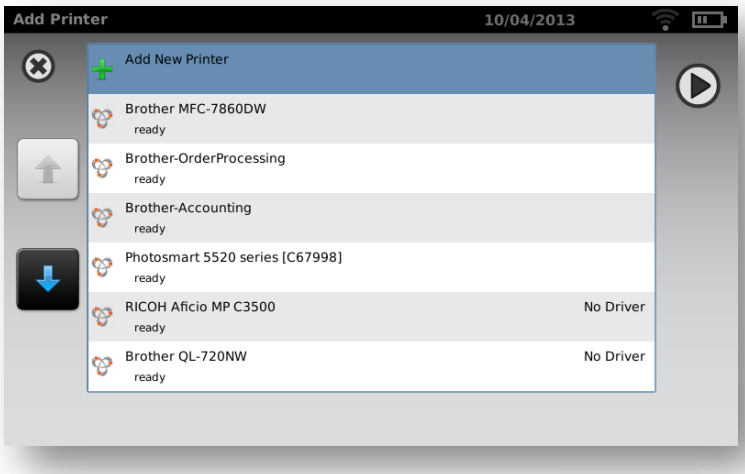

Figure 14

3. Review the printer details (Name, Driver and Location). To change or add settings touch the field you wish to change *(Figure 15)*. If you need to add a Driver, you can use the search feature by typing part of the driver name in the Search field.

   ***NOTE**: PCL drivers are available for non-HP printers. It is not guaranteed that every printer will work with the vision screener.*

4. Once changes have been made, select Save.

5. Once saved, the Print Test Page will appear dark.

6. A printer icon will appear in the menu bar indicating the job is processing. The number of jobs in the print queue will show up in the *Jobs* box at the top of the Printer Details screen, along with the current printer Status *(See Figure 15*).

Figure 15

NOTE: If you are having a problem with your printer or a print job is stuck in the queue, select the reset button to clear the print job and reset the printer.

7. Return to the Printers Available screen *(Figure 13)* and be sure to highlight the desired installed printer and set is as the default be selecting the "Set as Default" button.

Import & Export

1. From the "**Tools**" menu, select Import/Export and you will be directed to the Import/Export screen.

   Caution *– USB port is electrostatic sensitive. Be sure to take proper precautions to avoid potential ESD damage to the USB port.*

2. Insert a USB storage device into the USB port on the vision screener (Recommended USB size is 8GB or larger).

3. Once the USB device is detected, the Import and Export buttons will be available for selection and you will see the USB symbol in the upper right black bar next to the date. (Figure 16)

4. The Import button will only become available if the vision screener recognizes a valid import file. Number of import files found will be shown on the screen.

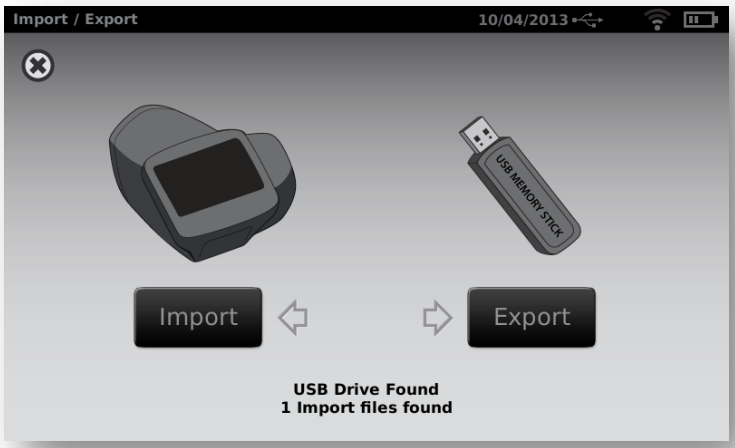

Figure 16

NOTE*:* If the buttons do not highlight within five seconds of inserting the USB drive, remove the USB, insert it into your PC and remove all files from the drive before attempting to retry.

Export

Select the Export button. If you wish to export one file containing no subject specific data select "Exclude Personal Data". If you do not choose this option, then all data will be exported. Select Export button again to begin the export process.

Wait until the message "Export Finished successfully" displays, select "ok" then you may safely remove the USB drive from the vision screener.

The exported folder name on the USB will be "Spot_SerialNumber_YYYYMMDD_HHMMSS" (the folder labeled "Spot_SerialNumber" will only contain screening data if inserted while screening subjects). It will contain:

- Spot Criteria file (located in the "import" folder).
- Spot Subjects Template file (located in the "db" folder).
- Spot Results file (located in the "db" folder).
- Spot Banner file (located in the "import" folder, will only be visible if custom banner was added).

Subject PDF files (located in the "pdf" folder).

***NOTE**:* If the USB drive is removed prior to export completion, data transfer may be incomplete or become corrupted as a result.

Import

With the import function, you can import:

- Updated criteria files (SpotCriteria.csv)
- Future, queued, screening files (SpotSubjects.csv or Location.csv By using a Location in the name of the file, this will default all subjects in the file to a location via the name of the file, ex LakeMary.csv would default to "LakeMary" as the location for all subjects in this file)
- Custom banner for the screening reports (banner.png)

The file must follow the correct naming convention for a successful import (i.e., banner.png, SpotCriteria.csv, SpotSubjects.csv. *Remember SpotSubjects can have a location as the name of the file*).

Vision Screener Criteria

To modify current screening criteria:

1. Perform an export and insert the USB drive into your PC.
2. Go to the USB drive folder and open the Spot folder that you just exported; select the "import" folder.
3. Copy the file "SpotCriteria.csv" to the top folder on the USB drive (the file cannot be within a folder). Once copied, open the file.
4. Make any desired changes using Microsoft Excel or compatible program.
5. Save file as a Comma Separated Value (.csv) file. You must make sure the file is called "SpotCriteria.csv". Eject the USB drive from your PC and insert into the vision screener.
6. Go to the "**Tools**" menu and select "Import/Export".
7. Select the "Import" button to import the updated criteria file.

8. To verify the file was imported successfully, go to the "**Tools**" menu and select Criteria; review new settings.

   NOTE: When custom criteria has been imported and is in use, there will also be a "Default" button at the bottom of the screen. This Default button will prompt the User to confirm they want to revert to the default criteria that was shipped with the device. By confirming, the custom criteria will be deleted from the vision screener and replaced with the default criteria.

Subjects

The vision screener gives you the ability to populate a subject list for "Queued" subjects.

1. Perform an export, once complete, remove the USB drive from the vision screener and insert it into your PC.
2. Select the Spot folder that was just created.
3. Select the "db" folder, then select the "SpotSubjects.csv" file.
4. The SpotSubjects.csv file contains six columns; do not change any of the column headings. Simply add information to the columns as shown below:

   NOTE: You may add a column before the Patient Id column and call it Location if you need to create specific locations for each subject.

   - **Patient ID**—You can use any combination of alpha, numeric characters and symbols.
     - This field is used for quick subject look-ups.
   - **First Name**—Enter the first name. Use any combination of alpha characters.
   - **Last Name**—Enter the last name. Use any combination of alpha characters.
   - **Date of Birth**—Enter the date of birth in the format MM/DD/YYYY. You can enter the age of subject in years, months or a combination of both. This field is **required** for the import to work.
     - For example: If a subject were 2 years and 10 months old, you would enter 2Y10M. Use numeric and alpha characters.
   - **Gender**—Select Male or enter M; select Female or enter F.
     - Alpha characters only; leaving the field blank will default to no gender identified.
   - **Eyewear**—Select None, Glasses, or Contacts. By leaving the field blank, 'None' will be set as the default.

After updating the import file:

1. Confirm the file is saved as a Comma Separated Values (.csv) file.

2. Verify file name is 'SpotSubjects.csv' or 'DesiredLocation.csv'.

   ***NOTE**:* If labeling your subject file(s) with a location, the vision screener will import all files found on the USB drive at the same time.

3. Follow the import procedures to load the file onto the vision screener. To verify the file was imported successfully:

4. Return to the Home screen and go to the Queue icon to view the new records.

Custom Banner

Welch Allyn offers the ability to add a custom banner to the bottom of the printable reports. Please note that Welch Allyn does not supply custom banners. You will need to create your banner using the specifics below:

- Banner files must be named "banner.png"
- No larger than 1MB
- Image must be 1376 x 240 pixels

To **add a custom banner**:

1. Place the banner.png file on the root/top-level directory of the USB.
2. Insert the USB in the vision screener. Go to Tools, then select Import/Export.
3. The import file option will highlight; select Import.

To **verify that the file was imported** successfully:

1. Screen a new subject or select a completed record and print the report.
2. Your new banner will be printed on the bottom of the report.

Web Access

When connected to a wireless network, the vision screener gives you the ability to view files from a web browser (Internet Explorer, Firefox, Safari, etc.) on a PC on the same network.

To **access the webserver** on the vision screener:

1. From your computer, open a web browser; enter the devices IP address in the address bar (this is located on the top black bar on the Home Screen).

2. You will be prompted to enter the username and password.

    - Username: *spot*
    - Password: *0000*

    NOTE: If you have enabled "Security" on your device, the password will be your four-digit pin code.

3. Default will go to the "report" folder. This contains the pdf folder where you can find subject PDF files.
4. To view the SpotResults.csv file change to the "db" directory.

Licensing

In order to use the screening functionality of the vision screener, the device needs to be licensed. If your device came new from the factory with this instruction document, your license is already installed and active. If you have updated the software on your device, the licensing will need to be updated as follows:

1. Connect an empty USB device to the vision screener USB port.
2. Go to tools, then the Spot License button.
3. After a moment, a dialog box will appear indicating that the registration file has been exported to the USB drive.
4. Send the file titled spot-[serial number].reg to Welch Allyn Support at customerservice@welchallyn.com.

Welch Allyn Support will review your registration file and email you back a valid license key. Once you receive the key, perform the following:

1. Save the file to the top level (root directory) of a USB Drive.
2. Insert the USB drive into the USB port on the vision screener.
3. From the Tools menu, select Spot License.
4. After a moment, a dialog box will appear indicating that the license file has been imported onto the device.

Basic Troubleshooting

System Restart

1. To power cycle the vision screener - press and hold the power button until a confirmation screen appears. Select Confirm to power off.
2. When the screen turns black, wait 30 seconds and then press the power button to turn the vision screener back on. Ensure the device has power by plugging in the power cord.

System Freeze

In the event the vision screener locks up and is unresponsive to touch, you will need to perform a hard system reset.

1. Press the power button.
2. If the Power Off window appears, select Confirm to shutdown the device.
3. If not, **press and hold** the power button until the screen goes black, then release the power button.
4. Wait about one minute then perform the normal start-up process.

   NOTE: This may cause some data loss (ex. printer configuration and subject data).

Printer Issues

Check that your printer is turned on and has sufficient ink or toner:

1. Print a test print page directly from the printer.

After you confirm your printer is in proper working order:

2. Verify the printer is on a local network by printing to the printer from a PC on the same local network.

If all of the above are in working order:

3. Perform a "System Restart" (see above).

Wireless Issues

If you encounter problems connecting to a wireless network:

1. Check for the Wireless Icon in the upper right corner. If the icon is red, try power cycling the vision screener first.
2. Verify all network settings are entered correctly.

3. If the settings are correct, try turning the vision screener off, then back on.
4. Check on the "Home" screen to see if your network name and IP address is identified in the upper left corner in the black bar.

   NOTE: Restarting helps to reinstate the connection to the network.

5. If the connection does not automatically reconnect, go to Tools, Network, select Security Type, reselect the correct type (None, WEP, WPA) then select the highlighted "Ok". This should re-instate the network connection.

System Messages

Specific system messages may appear while operating the vision screener. If so, the information below will assist you in identifying what the messages indicate:

Message Text	Message Actions	Meaning	Action
Sorry for the inconvenience. We need to reboot the device.	Ok or Cancel	Screening mode has encountered a problem and the device needs to be restarted.	Select Ok and the device will power cycle itself. If the problem persists, contact Welch Allyn Support.
Problem Encountered. The vision screener needs to reboot.	Reboot	The system was not able to start and has attempted to correct the issue	Select Reboot and try again. If problem persists, contact Welch Allyn Support.
The screening system is not available.	None	The Exam system did not initialize, or is unresponsive.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
The screening system is not initialized.	None	The Exam system did not initialize, or is unresponsive.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
The vision screener has not finished saving the previous screening.	None	The system has detected that it is still saving files to disk from a previous exam.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
Un-calibrated Device	None	The system has not been able to read the device configuration file.	Power cycle the device. If problem persists, contact Welch Allyn Support.

For more information on troubleshooting or error messages, contact Welch Allyn's support team (refer to the last page of this manual for additional contact information).

Technical Description

General

- The vision screener model VS100 will be referred to as The Vision Screener.
- This vision screener DFU document is valid for software version 2.1.4.
- The external power supply/charger supplied is a Class I equipment and the vision screener is also a Class I equipment when connected to the external power supply/charger.
- The vision screener is internally powered by equipment (battery) when not connected to the external power supply/charger.
- Protection against electric shock, no applied part.
- The vision screener is rated IPX0 and thus not protected from the ingress of water.
- The vision screener does not require sterilization or disinfection. DO NOT use cleaners that contain organic solvents to clean the vision screener's housing or front glass. For stubborn dirt, try using a soft cloth with a small amount of water or a non-abrasive cleaner.
- The vision screener is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The vision screener is suitable for continuous operation.
- The vision screener quickly and easily detects vision issues across all age groups starting at 6 months.
- The vision screener helps ensure children have an opportunity to reach their full potential. Designed to work as easily with toddlers as with teenagers; the device provides reliable data in seconds. With the vision screener, educators, healthcare professionals, and charitable organizations can now confidently assess eyesight for all ages. The vision screener is powered by sophisticated technology that quickly detects the indication of the following vision issues:
    - Myopia (Near-sightedness)
    - Hyperopia (Far-sightedness)
    - Anisometropia (Unequal refractive power)
    - Astigmatism (Blurred vision, eye structure problem)
    - Anisocoria (Pupil size deviations)
    - Strabismus (Eye misalignment, Gaze)
- In just seconds, the vision screener provides a comprehensive, reliable analysis that enables informed decision making about the need for care with a vision specialist.
- Welch Allyn suggests a battery replacement, at an appointed Welch Allyn repair facility, every 2.5 years at the owner's expense. The vision screener regular maintenance consists of wiping dust or dirt off the front glass surface and the LCD display as needed.

- The USB port shall only be used for software download/upload via a USB flash drive and shall not be cable connected to any other device.
- The power supply/charger's supplied with the vision screener have the following characteristics:

Mfg: International Power Corporation, Elpac Power Systems		Mfg: SL Power Electronics
Model: MW4015-760F-NC-BK		Model: MENB1040A1503F01 or MEMB1040A1541F01
Input Voltage: 85 – 264VAC (100 – 240VAC Nominal)	OR	Input Voltage: 90 – 264VAC (100 – 240VAC Nominal)
Input Frequency: 47 – 63 Hz		Input Frequency: 47 – 63 Hz
Input Current: < 1A rms		Input Current: 100VAC: 1.1A
Avg. Efficiency: 86.4% @ 115VAC; 85.7% @ 230VAC		Avg. Efficiency: 81-87% @ 0-50 W, ≥87% @ >51 to 250

Environmental Protection

This device contains Lithium ion cells and other electronic materials. Please contact your local government authorities for proper electronic waste recycling or disposal methods at end of life.

EMC Information

This equipment has been tested and found to comply with the limits for a Class A digital devices, pursuant to Part 15 of the FCC Rules. This medical device equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The maximum wireless signal rate for the system is derived from IEEE Standard 802.11b/g/n specifications. Actual data throughput will vary. Network conditions and environmental factors, including the volume of network traffic, building materials and construction, and network overhead, may lower actual data throughput rate. Environmental conditions will adversely affect wireless signal range.

Electromagnetic Compatibility

This product conforms to the EMC standard (IEC 60601-1-2:2007).

- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Connectors should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.
- ESD protection mark may be used in lieu of protective covers.
- Portable and mobile RF communications equipment can effect medical electrical equipment.
- The use of accessories and cables other than those supplied with the instrument exception for cables sold by the manufacturer of the equipment as replacement parts, may result in increase emission or decrease immunity of the equipment or system.
- The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

EMC Table

Emission Guidance		
The Welch Allyn vision screener is intended for use in the electromagnetic environment specified below. The operator or the user of the device should assure that it is used in such an environment.		
Emission Test	***Compliance***	***Electromagnetic environment guide***
RF Emission Cispr 11	Group 1	The vision screener must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emission Cispr 11	Class A	The vision screener is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supplies building used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Class A Compliant	
Voltage Fluctuation/flicker Emission IEC 61000-3-3	Compliant	

Immunity Guidance

The vision screener is manufactured to work in the electromagnetic environment specified below. The operator or user should make sure it is used within those environmental conditions.

Immunity Test	*Test level EN 60601-1-2*	*Conformity Level*	*Electromagnetic environment guide*
Electrostatic Discharge (ESD) EN 61000-4-2	± 8kV air ± 6kV contact	Non-conforming This unit is sensitive to ESD and may require resetting	The floor should be in wood, concrete or ceramic tile. If the floor is covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst EN 601000-4-4	±2 kV high voltage power line	±2 kV high voltage power line	The quality of the power supply should be that one of a typical commercial or clinical environment.
Surge EN 61000-4-5	Differential mode: ±1 kV Common mode: ±2kV	Differential mode: ±1 kV Common mode: ±2kV	The quality of the power supply should be that one of a typical commercial or clinical environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% UT (>95% dip of UT) for 0,5 cycle 40% UT (>60% dip of UT) for 5 cycle 70% UT (>30% dip of UT) for 25 cycle <5% UT (>95% dip of UT) for 5 seconds	<5% UT (>95% dip of UT) for 0,5 cycle 40% UT (>60% dip of UT) for 5 cycle 70% UT (>30% dip of UT) for 25 cycle <5% UT (>95% dip of UT) for 5 seconds	The quality of the power supply should be that one of a typical commercial or clinical environment. If the user requests a continuous functioning during power supply interruptions, it is recommended a backup power supply unit (UPS) or battery.
Magnetic field at power frequency EN 61000-4-8	3 A /m	3 A /m	Power frequency magnetic fields should have characteristic levels of a typical commercial or clinical environment.

Immunity Radio Frequency Guidance

The vision screener is manufactured to work in the electromagnetic environment specified below. The operator or user should make sure it is used within those environmental conditions.

Immunity Test	*Test level EN 60601-1-2*	*Conformity Level*	*Electromagnetic environment guide*
Conducted RF EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	The portable and mobile devices with RF communication shouldn't be used near any part of the device, including cables, except when they follow the recommended safety distance for separation, calculated with the equation applicable to the frequency of the transmitter. Recommended safety distance for separation: D= 1,2 x √P from 150kHz to 80MHz D= 1,2 x √P from 80MHz to 800MHz D= 2,3 x √P from 800MHz to 2,5GHz Where P is the nominal maximum power of the transmitter output expressed in Watts (W) as specified by the transmitter manufacturer and d is the recommended separation distance expressed in meters (m).
Radiated RF EN 61000-4-3	3 V/m from 80MHz to 2.5GHz	3 V/m from 80MHz to 2.5GHz	
Surge EN 61000-4-5	Differential mode: ±1 kV Common mode: ±2kV	Differential mode: ±1 kV Common mode: ±2kV	

The field intensity of the fixed RF transmitters, as checked in an electromagnetic investigation of the locus, should be less than the conformity level for each range of frequency.

It is possible to have interference near devices marked with the symbol:

Recommended separation distance between portable or mobile devices for radio communication and the device

The vision screener is manufactured to work in an electromagnetic environment in which the radiated RF disturbances are controlled. The operator or user of the device could prevent electromagnetic interferences by assuring a minimal distance between the portable or mobile RF communication devices (transmitter) and the device as recommended in the chart below, in respect of the output maximum power of the radio-communication devices.

Output maximum frequency (m) nominal power of the transmitter (W)	*Separation distance at the transmitter Output maximum frequency (m)*		
	from 150kHz to 80MHz D= 1,2 x ÖP	*from 80MHz to 800MHz D= 1,2 x ÖP*	*from 800MHz to 2,5GHz D= 2,3 x ÖP*
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the transmitter with output maximum nominal power not reported above, the separation distance d in meters can be calculated using the applicable equation at the frequency of the transmitter, where P is the output maximum nominal power of the transmitter in Watts specified by the transmitter manufacturer.

Notes: (1) At 80 MHz and 800 MHz it is applicable the higher frequency range.

(2) This line guide could not be applicable in every circumstance. The electromagnetic propagation is affected by the absorption and the reflection of structures, people or objects.

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: *This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.*

Warning: Changes or modifications not expressly approved by Welch Allyn could void the user's authority to operate the equipment.

IC Compliance Statement

This Class A digital apparatus complies with Canadian ICES-003.

Specifications

Dimensions (in): 8½ x 6¾ x 4¾ (LxWxH)

Weight (lbs.): ~2.55

Wireless Network: 802.11 b/g/n

Operating Temperatures (°C): +10 to +40

Operating Humidity: 30% to 75% Relative Humidity (non-condensing)

Storage/Shipping Temperatures (°C): 0 to +50

Storage/Shipping Humidity: 0% to 75% Relative Humidity (non-condensing)

Storage/Shipping Atmospheric Pressure: 800 hPA to 1060 hPA

Expected Battery Life: 2.5 Years (Under Normal Usage)

Measurements

Refraction

Spherical Equivalent:

- Range: -7.50D to +7.50D in 0.25D increments
- Accuracy: -3.50D to 3.50D, ± 0.50D
  -7.50D to < -3.50D, ± 1.00D
  > 3.50D to 6.00D, ± 1.00D

Cylindrical:

- Range: 0.00D to +3.00D in 0.25D increments
- Accuracy: 0.00D to 1.50D, ± 0.50D
  > 1.50D to 3.00D, ± 1.00D

Cylindrical Axis:

- Range: 1 to 180 degrees in 1-degree increments
- Accuracy: ± 5 degrees (for cylinder values > 0.5D)

Pupil size:

- Range: 4.0 mm to 9.0 mm in 0.1 mm increments
- Accuracy: ± 0.1mm

Pupil distance:

- Range: 35mm to 80 mm in 1 mm increments
- Accuracy: ± 1 mm

Time per measurement: 1 s

Measuring distance: 1 m ± 5 cm

Fixation target: Random visual pattern and audible sound

Measurement principal: Optical reflex

Symbols

	DC Power
IPX0	Ingress Protection
	Battery Inside (Not User Replaceable)
	Battery Charging (Flashing) Charged (Continuous)
	Power On/Off
	Non-ionizing Electromagnetic Radiation
	Refer to Instruction Manual
	This symbol is applicable for EC member countries only. To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other
	ESD Protection Mark
	USB Port (Software Updates Only)
	DC Power Input Port, Center Pin Positive

	Battery Status/Level Indicator (Graphics Display Icon)
	Connected to the Wireless Network (Graphics Display Icon)
	No Wireless Network in Range (Graphics Display Icon)
	No IP Address Assigned by the Router (Graphics Display Icon)
	Unknown Network (Graphics Display Icon)
	Cannot Connect to Configured Network (Graphics Display Icon)
	Sound Off (Graphics Display Icon)
	Sound On (Graphics Display Icon)
	Continue Icon
	Back Icon
	Exit to Previous Screen or Main Menu
	Print Job in Progress

Limited Warranty

Welch Allyn provides the following limited warranty for the vision screener device:

Welch Allyn provides a limited repair or replacement warranty and agrees and warrants only that Equipment (Equipment means the medical device outlined in this document, model number VS100) will be fit for its intended purpose and without material defect in workmanship and materials for the one (1) year period following delivery date. Equipment shall not be considered defective if it is a different color than shown in Welch Allyn's materials and no warranty is made relating to color. All requests for warranty work are subject to Equipment inspection at Welch Allyn contracted facilities. End User must ship the Equipment for inspection to Welch Allyn's dedicated warranty and repair facility at User's expense. Misuse, improper usage and/or handling, dropping, improper repairs, improper maintenance and care, or accidental, abusive, or negligent treatment of the Equipment will invalidate Welch Allyn's warranty. Welch Allyn shall not be responsible after delivery of the Equipment to End User for maintenance or support of the Equipment, only for warranty services. This warranty is not a guarantee that the Equipment will not through use or handling develop wear, tear, and mechanical breakdown from time to time, the repair of which is the sole responsibility of the End User if beyond the stated warranty period or excluded from warranty coverage for the reasons stated hereinabove. If a returned item of Equipment is evaluated and found defective and the warranty for such Equipment is in force, Welch Allyn will bear the cost of shipping the repaired or replacement Equipment to End User; otherwise, all shipping costs will be borne solely by the End User. No statement, remark, or representation of any employee or representative of Welch Allyn may vary this limited warranty unless in writing and signed by an officer of Welch Allyn. This warranty shall be void if User loads or uses any software programs or applications on Equipment other than the software installed and licensed to User by Welch Allyn. This warranty shall be void if Welch Allyn finds that Equipment has been opened or the hardware has been altered in any way. All warranty claims must be made directly to the Welch Allyn support team within the warranty period.

Welch Allyn does not warrant accessories.

Contact Welch Allyn

If you have questions about any Welch Allyn product, contact Welch Allyn Customer Support: http://www.welchallyn.com/en/other/contact-us.html.

Address:

Welch Allyn, Inc.

4341 State Street Rd

Skaneateles Falls, NY 13153-0220 USA